UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

PRODUCTS LIABILITY LITIGATION	Dkt. No. 1:13-md-2419-RWZ	
This Document Relates to Suits Naming:		
Saint Thomas Outpatient Neurosurgical Center, LLC		

AFFIDAVIT OF JOHN W. CULCLASURE, MD

STATE OF TENNIESSEE	\	

COUNTY OF DAVIDSON

Comes John W. Culclasure, MD, after first being duly sworn, and states as follows:

- 1. I am over 18 years of age, have personal knowledge of the facts contained herein, and am competent to testify to same.
- 2. I am currently a licensed anesthesiologist, and I was licensed during all times relevant hereto.
- 3. I am currently the Medical Director at Saint Thomas Outpatient Neurosurgical Center ("STOPNC"), and I was the Medical Director at STOPNC, at all times relevant hereto.
- 4. STOPNC is currently licensed as an ambulatory surgery center and accredited by the Joint Commission, and it was licensed as an ambulatory surgery center and accredited by the Joint Commission during all times relevant hereto.
- 5. STOPNC performs the following procedures to treat its patients' pain: steroid injections, radiofrequency ablations (denervations), spinal cord stimulator trials, diagnostic facet joint injections, hardware blocks, and nerve root blocks. The same was true in 2012.
- 6. STOPNC procured methylprednisolone acetate ("MPA") from the New England Compounding Center ("NECC") for use by physicians in steroid injections. STOPNC paid \$6.50 for each one milliliter vial containing 80 milligrams of MPA.¹

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¹ See invoice from NECC attached as Exhibit 1.

- 7. At STOPNC, the Plaintiffs underwent epidural steroid injection procedures performed by a licensed anesthesiologist following a diagnosis of, and as treatment and care for, pain related to spinal nerves, intervertebral discs, and facet joints. I personally performed many of the Plaintiffs' steroid injection procedures.²
- 8. For example, Plaintiff Mae Parman was referred to STOPNC for epidural steroid injections to treat back, hip, and leg pain, believed to have been caused by lumbar stenosis.³
- 9. Prior to undergoing epidural steroid injection procedures at STOPNC, the Plaintiffs signed a consent form.⁴
- 10. I charged the Plaintiffs and/or their insurers a physician fee for my professional services during the epidural steroid injection procedures. Howell Allen Clinic, my employer, submitted a bill for this fee to the Plaintiffs or their insurers.⁵
- 11. STOPNC charged the Plaintiffs and/or their insurers a facility fee of approximately \$1,034,6 which was a single, global fee for the steroid injections that covered all aspects of the procedure furnished by STOPNC, including:
 - A licensed registered nurse to assess the patient's condition prior to the procedure, assess the patient's condition post-procedure, and discharge the patient
 - b. A licensed practical nurse, certified medical assistant, or a certified radiology technician to assist the physician in performing the procedure
 - c. Use of STOPNC's facility, including a patient room (pre and post-procedure) and an operating room
 - d. Use of STOPNC's equipment, including (1) a fluoroscopy (x-ray) machine to provide the physician with a real-time view of the patient's spine to help the physician ensure the medication was being administered in the epidural space and (2) equipment to monitor the patient's vital signs
 - e. The medications administered during the procedure, including the steroid, contrast dye, saline, and local anesthetic
 - f. The medical supplies used during the procedure, including latex gloves

⁵ See, e.g., excerpts from Plaintiff Mae Parman's Howell Allen billing records attached as Exhibit 5.

² See, e.g., excerpts from Plaintiff Mae Parman's STOPNC medical records attached as Exhibit 2 (Case No. 1:13-cv-12433).

³ See, e.g., excerpts from Plaintiff Mae Parman's Howell Allen medical records attached as Exhibit 3.

⁴ See, e.g., consent form signed by Plaintiff Mae Parman attached as Exhibit 4.

⁶ The charge varied somewhat based on the precise type of injection procedure performed.

- g. Administrative services such as recordkeeping, billing, and scheduling.⁷
- 12. I typically administer 80 mg of MPA (a single vial) to patients during epidural steroid injections. However, for some patients, I administer 120 mg (a vial and a half) during their procedures. The same was true in 2012.⁸
- 13. STOPNC's charge for the procedure remains the same regardless of the number of vials of MPA administered.⁹
- 14. If some MPA remained in a vial, such as when I used 120 mg of MPA (a vial and a half), the remainder was destroyed.
- 15. During a radiofrequency ablation, the nerve supply to painful joints is cut by the heat generated at the tip of the needle, providing pain relief.
 - 16. Radiofrequency ablations do not rely on medication to provide pain relief.

⁸ See, e.g., excerpts from Plaintiff Mae Parman's STOPNC medical records attached as Exhibit 2.

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⁷ See, e.g., excerpts from Plaintiff Mae Parman's STOPNC billing records attached as Exhibit 6.

⁹ Compare STOPNC's bill and corresponding medical record for Mae Parman's July 30, 2012 procedure (showing that 80 mg of MPA was administered) with STOPNC's bill and corresponding medical record for Mae Parman's August 20, 2012 procedure (showing that 120 mg of MPA was administered, with no change to STOPNC's charge).

EXHIBIT 1 NECC Invoice



New England Compounding Center, Inc. PO Box 4146 Woburn, MA 01888-4146 Ph. 508-820-0606 Fx. 508-820-1616

Invoice

Date	Invoice #
8/13/2012	225489

ST. THOMAS OUTPATIENT NEUROSURGICAL 4230 HARDING ROAD, SUITE 901 NASHVILLE, TN 37205 ATTN: MARLESE ALLEN

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ST. THOMAS OUTPATIENT NEUROSURGICAL 4230 HARDING ROAD, SUITE 901 NASHVILLE, TN 37205 ATTN: DEBRA SCHAMBURG

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Excerpts from Plaintiff Mae Parman's STOPNC medical records (Case No. 1:13-cv-12433)

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		ation n	Time Printed 8/20/2012 1:17 PM		Age 82 Years	D.O.B. 1/22/1930	Sex Female	Height	Medical Recor	d #	
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Surgeon			Start	Stop	Total	Procedure(s)		· · · · · · · · · · · · · · · · · · ·	 	Code(s)	
sargeon		Anes				Fluoroscopy Lumbar Translamin	ar ESI			Code(s)	
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8/20 1:06 PM	noted otherwise.) Methylprednisolone acetate		V X				9		8		
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Excerpts from Plaintiff Mae Parman's Howell Allen medical records (Case No. 1:13-cv-12433)

2011 Murphy Ave., Suite 301, Nashville TN 37203 (615) 327-9543 (800) 668-9410

Fax: (615) 327-8471 Web: www.howellallen.com

Provider Everette I. Howell Jr. MD

Patient: Parman, Mae L.

DOB 1/22/1930

MRN 334142

DATE OF SERVICE: 06/18/12

Mae Parman is seen in the office today and now is retired. She continues to have pain in her back and increasing pain in the hip and down to the left leg. She has had an X-stop and still is limited in her activity.

In July 2010 she had an extensive operation for a hiatal hernia and so there is question about whether she can take any nonsteroidals.

Today her temperature is 97.9, blood pressure 151/84, pulse is 77. She gives a cogent history. She has full range of motion of her neck. She has no upper extremity numbness or weakness. She has diminished range of motion of her back with spasm. She walks on heels or toes with a positive Lasegue bilaterally.

IMPRESSION: Symptomatic lumbar stenosis, history of hiatal hernia repair with partial gastrectomy.

I have asked her to have an MRI scan of the lumbar spine and will see her back in the office to go over the study. While she may not be able to take nonsteroidals an epidural may be a reasonable option.

EIH / 10053/ghw/rcd

Letter to Deepinder S. Bal, M.D. dated 06/21/12.

Electronically signed by: Everette I. Howell, M.D. on 6/21/2012

Progress Note

Patient Name:

Mae Parman

Patient ID:

334142

Birthdate:

Sex:

Female January 22, 1930 Visit Date:

June 18, 2012

Provider:

Everette I. Howell, Jr. MD

Location:

BNT Howell Allen Clinic

2011 Murphy Avenue Suite 301

Nashville, TN 372032023

Location Phone:

Location Address:

(615) 327-9543

Assessment

Spinal stenosis, unspecified region 724.00

<u>Plan</u>

Orders

o MRI Lumbar Spine w/out HAC APPT WITH EIH TO FOLLOW @ 10 (72148) - 724.00 - 07/09/2012

Instructions

o Ordered MRI APPT 7-9-12 @ 8:30 ARRIVAL 8:00 AM

Disposition

Patient scheduled to see Dr. Howell

Electronically Signed by: Fayrene Rader, -Author on July 5, 2012 08:16:27 AM

2011 Murphy Ave., Suite 301, Nashville TN 37203 (615) 327-9543 (800) 668-9410

Fax: (615) 327-8471 Web: www.howellallen.com

Provider Everette I. Howell Jr. MD

Patient: Parman, Mae L.

DOB 1/22/1930

MRN 334142

DATE OF SERVICE: 07/09/12

Ms. Mae L. Parman was seen in the office on 07/09/12. There has been no change in her exam. I have gone over her study with her. This does show that she has marked stenosis at L3-4 and L4-5. I do think she will require an operation for this. Since she has had a prior procedure, she would need an open procedure. She is not ready to consider this and so may benefit from an epidural.

She is to decide how she wishes to proceed.

I have gone over her study with her and have given her a copy of the report. She will call me back and let me know.

EIH / 10053/swm

cc: Deepinder S. Bal, MD and Ms. Mae L. Parman with letter 07/11/12

Electronically signed by: Everette I. Howell, M.D. on 7/11/2012

Progress Note

Patient Name:

Mae Parman

Patient ID:

334142

Sex:

Female

Birthdate:

January 22, 1930

Visit Date:

July 9, 2012

Provider:

Everette I. Howell, Jr. MD

Location: **Location Address:** BNT Howell Allen Clinic

2011 Murphy Avenue Suite 301 Nashville, TN 372032023

Location Phone:

(615) 327-9543

<u>Vitals</u>

												BMI	
Date	Time	BP	Position	Site	L\R	Cuff Size	HR	RR	TEMP(°F)	WT	HT	kg/m²	BSA m ² O2 Sat HC
07/09/2012	10:09 AM	156/88	Sitting				77 - R		98	155lbs 0c	oz 5' 6"	25.02	1.81

<u>Assessment</u>

Lumbar Stenosis 724.02

<u>Plan</u>

Orders

o Lumbar Epidural Steroid Injection X 2 (62311) - 724.02 - 07/11/2012

Instructions

- Will Call back
- o Patient will be scheduled for Epidural Steroid Injections.

Electronically Signed by: Fayrene Rader, -Author on July 11, 2012 03:45:18 PM

STOPNC consent form signed by Plaintiff Mae Parman (Case No. 1:13-cv-12433)

ST. THOMAS OUPATIENT NEUROSURGICAL CENTER NASHVILLE, TENNESSEE

		ATION, ADMINIST NG CONSENT FOR			ID RENDERING OF OTHER A SE OF	MEDICAL
	·	mae		man	PARMAN, MAE L. SC28239	07/30/12
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IHI	S PARAGRAPH A	UTHORIZES THE			DR. HOWELL	
			Olin Cu	0000000	M.D. and associates or assist	anda af bia
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	alternative trea	tments have been ex	xplained to me t	y the doctor. Alt	hough it is impossible for the	e doctor to
	inform me of ev	ery possible complic	ation that may	occur, the doctor i	has answered all of my quest	ions to my
	satisfaction. As	s with ALL types of	surgery, there i	s the possibility o	f other complications due to	anestnesia,
	drugs, reactions	or other factors wi	hich may involve	other parts of my	y body, including a possibility	ot brain
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5.	I authorize the	administration of tr	ransfusions of b	lood products to t	he above patient as may be a	leemed
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6.			, pharmacists, S	t. Thomas Outpati	ient Neurosurgical Center, or	other
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		tion as instructed by				
9.	I hereby consei	nt to the presence o	of M_{20}	1012/	(Name and Title)	during my
	surgery for the	sole purpose of obs	servation for ed	ucational reasons.	I understand that this indiv	idual(s) will
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10.					adult to drive me home and t	o be with me
		r (24) hours followin		·		
11.				uring my stay as w	vell as video taping or photog	raphy of my
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		laims of any kind for				
12.					nership interest in the St. Th	omas
	Outpatient New	urosurgical Center.	If I choose to a	o to another healt	th care facility for this proce	dure, it will
		upon my relationship			·	•
13.					sponsibility for loss and/or d	amage to
·					atient Neurosurgical Center.	-

UNDERSTAND IT AND THE POSSIBLE RISKS, CO THE SURGERY. I ACCEPT ON BEHALF OF MYSELF THESE PARAGRAPHS.	MPLICATIONS AND BENEFITS THAT CAN RESULT FROM FAND/OR THIS PATIENT ALL OF THE ITEMS LISTED IN
Date Witness to Signature If patient is a minor or unable to sign, complete the	following:
Patient is a minorPatient is unable	e to sign because
Father Gu	uardian
Mother W	/itness to Signature
REQUEST FOR ADMINISTRATION OF ANESTHE I understand that it will be necessary to be placed a operation, and I consent to the use of anesthesia as surgeon and nurse anesthetist with the EXCEPTION	under anesthesia in order to perform the above described deemed necessary and appropriate by my anesthesiologist,
not limited to, adverse drug reactions, brain damage to vocal cords, respiratory problems, minor pain and backaches or warsening of pre-existing disease(s).	the surgical procedure itself. These risks may include, but are, death, nerve injury, damage to teeth or dental work, damage discomfort, damage to arteries or veins, headaches, The purpose, necessity and risk of anesthesia have been
I DECLARE AND REPRESENT THAT I HAVE READ or warranty has been made as to the result of the c	THE ABOVE AND UNDERSTAND IT IS TRUE. No guarantee inesthetic procedures.
Witness	Signature (of person authorized to consent)
Date and Time	Relationship to Patient

Excerpts from Plaintiff Mae Parman's Howell Allen billing records (Case No. 1:13-cv-12433)

Case 1:13-md-02419-RWZ Document 2464-1 Filed 12/03/15 Page 21 of 25

Parman, Mae L. [334142] P O Box 273 Fairview, TN 37062

5/6

Account Information Report Include:All

Page: Date: Time:

09/25/2013 12:05:49 PM

Show: Unexpanded Details

ੁ_ osting Date	Service Date	User	Description	Amount	Balance
10/18/2012	10/02/2012	CK	NC [0.00 x 1] Billable: Howell, Everette I. Jr. MD; Rendering: Howell, Everette I. Jr. MD Practice Location: BNT Howell Allen Clinic; Service Location: BNT Howell Allen Clinic; Referring: Bal, Deepinder S. MD	\$0.00	\$0.00
N N			[788.87] CoPay: \$0.00; Visit Type: Misc. Dictation; Visit ID: 150225; Stmt Recipient: Mae Parman Void		
09/28/2012		NM	Insurance Payment [16.53] AARP; Check; Insurance Plan ID: 1564 Batch: 8515 BATCH 6	(\$16.53)	
09/05/2012		NM	Contractual Adjustment [482.33] Medicare; Insurance Plan ID: 1412 (ERA) Batch: 8199 501	(\$482.33)	
09/05/2012		NM	Insurance Payment [66.14] Medicare; Check; 886397683; Insurance Plan ID: 1412 (ERA) Batch: 8199 501	(\$66.14)	
09/04/2012		NM	Insurance Payment [16.53] AARP; Check; Insurance Plan ID: 1564 Batch: 8186 BATCH 16	(\$16.53)	
08/21/2012	08/20/2012	CJH	62311 [565.00 x 1] Billable: Culclasure, John W. MD; Rendering: Culclasure, John W. MD Practice Location: St Thomas Office; Service Location: St Thomas OP Neurosurgical CTR; Referring: Howell, Everette I. Jr. MD [724.4 724.02] CoPay: \$0.00; Visit Type: Procedure; Visit ID: 140093; Stmt Recipient: Mae Parman	\$565.00	\$0.00
08/17/2012		NM	Injection, single (not via indwelling catheter), not including n Contractual Adjustment [482.33] Medicare; Insurance Plan ID: 1412 (ERA)	(\$482.33)	
08/17/2012		NM	Batch: 7973 BATCH 1701 Insurance Payment [66.14] Medicare; Check; 886308124; Insurance Plan ID: 1412 (ERA) Batch: 7973 BATCH 1701	(\$66.14)	
08/15/2012		NM	Insurance Payment [13.15] AARP; Check; Insurance Plan ID: 1564 Batch: 7947 BATCH 3	(\$13.15)	
08/15/2012		NM	Insurance Payment [74.59] AARP; Check; Insurance Plan ID: 1564 Batch: 7947 BATCH 3	(\$74.59)	
08/02/2012	07/30/2012	CJH	62311 [565.00 x 1] Billable: Culclasure, John W. MD; Rendering: Culclasure, John W. MD Practice Location: St Thomas Office; Service Location: St Thomas OP Neurosurgical CTR; Referring: Howell, Everette I. Jr. MD [724.4 724.02] CoPay: \$0.00; Visit Type: Procedure; Visit ID: 136235; Stmt Recipient: Mae Parman	\$565.00	\$0.00
₹ %)7/25/2012		NM	Injection, single (not via indwelling catheter), not including n Contractual Adjustment [33.25] Medicare; Insurance Plan ID: 1412 (ERA)	(\$33.25)	
∑ 37/25/2012		NM	Batch: 7657 BATCH 2501 Contractual Adjustment [945.03] Medicare; Insurance Plan ID: 1412 (ERA) Batch: 7657 BATCH 2501	(\$945.03)	
2)7/25/2012		NM	Insurance Payment [298.38] Medicare; Check; 886188941; Insurance Plan ID: 1412 (ERA) Batch: 7657 BATCH 2501	(\$298.38)	
ട്ട്)7/25/2012		NM	Insurance Payment [52.60] Medicare; Check; 886188941; Insurance Plan ID: 1412 (ERA) Batch: 7657 BATCH 2501	(\$52.60)	
್ಲ್ Э7/19/2012		NM	Insurance Payment [13.15] AARP; Check; 885985320; Insurance Plan ID: 1564 Batch: 7598 BATCH 7	(\$13.15)	

Excerpts from Plaintiff Mae Parman's STOPNC billing records (Case No. 1:13-cv-12433)

Case 1:12-ma- 02419-RWZ 6 100 6 10 12/03/15 Page 23 of 25

BUSINESS OFFICE 615-341-7579

ST THOMAS NEUROSURGICAL O/P CTR, LLC P 0 BOX 305172 DEFT 16 NASHVILLE, TENNESSEE 37230-5172

LOCATION: ST THOMAS OF NEUROSURGICA PT-0066 PAGE: 1

MAE L PARMAN BILLING DATE: 11/19/12

P 0 BOX 273

FAIRVIEW TN 37062 AMOUNT DUE : 0.00

BILL TO: PARMAN MAE CHART #: 5C28239

DATE	POS PROC	DESCRIPTION MAE	CHARGES	CREDITS	BALANCE
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07/30/12	62311	INJECTION SINGLE DIAGNOSTIC OF	1,034.00		1034.00
07/30/12		ADDITIONAL DIAGNOSIS	0.00		1034.00
08/02/12		MEDICARE # 981591 Filed			
08/20/12		AARP HEALTH CARE OPTIONS # 981	592 Filed		
08/17/12		PAYMENT MEDICARE OF TENNEC# 9		233.59-	800.41
08/17/12		Co-ins 58.40			
08/17/12		WRITE-OFF MEDICARE OF TENNEC#	981591	742.01-	58.40
		MAE			
		SAINT THOMAS OUTPT NEUROSURG			
08/20/12	62311	INJECTION SINGLE DIAGNOSTIC O	1,034.00		1092.40
08/20/12		ADDITIONAL DIAGNOSIS	0.00		1092.40
08/21/12		MEDICARE # 985921 Filed			
09/13/12		AARP HEALTH CARE OPTIONS # 985	922 Filed		
09/06/12		PMT AARP HEALTH CARE OPTION=#	981592	58.40-	1034.00
09/12/12		PAYMENT MEDICARE OF TENNEC# 98	85921	233.59-	800.41
09/12/12		Co-ins 58.40			
09/12/12		WRITE-OFF MEDICARE OF TENNEC#	985921	742.01-	58.40
09/24/12		PMT AARP HEALTH CARE OPTIONC#	985922	58.40-	0.00

CURRENT/30-60 BAYS/60-90 BAYS/ >90 BAYS/ TOTAL 0.00 0.00 0.00 0.00 0.00 TOTAL DUE 0.00

> ST THOMAS OP NEUROLOGICAL CENT P.O. BOX 305172 DEPT16 NASHVILLE TN 37230-5172

LUCATION: ST THOMAS OP NEU

PHONE : 615 341 7579 REFERRING DOCTOR : HOWELL JR MD

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